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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,470	01/21/2004	Wei Shao	CL001204-DIV	1815

25748 7590 10/31/2005

CELERA GENOMICS
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
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ROCKVILLE, MD 20850

EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,470	SHAO ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *1,2,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *notice to comply*.

DETAILED ACTION

1. Applicant's amendment, filed 8/15/05, is acknowledged.

Claims 4-23 have been cancelled.
Claims 1-3 have been amended.
Claims 24-38 have been added.
Claims 1-3 and 24-38 are pending.

2. Applicant's election with traverse of group II, drawn to antibodies, claim 3 and newly added claims 24-36, in the reply filed on 8/15/05 is acknowledged.

Applicant's traversal is on the grounds that it would not be an undue burden to examine the polypeptide of group I along with the antibody of group II, since the search is substantially similar. This is not found to be persuasive because the polypeptides and antibodies are distinct products due to different structures and functions. In addition, antibodies and polypeptides are recognized divergent subject matter, as exemplified by their different classifications. Therefore these products are distinct and independent, and searches for both would place an undue burden upon the examiner. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

The requirement is still deemed proper and is therefore made FINAL.

Therefore, Claims 1-2 and 37-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 3 and 24-36 read on the elected invention and are being acted upon.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth herein.

Applicant is required to submit a corrected CRF, Sequence Listing, and Statement that the contents are identical. The CRF

is missing mandatory numeric identifiers <150> and <151>, prior applications and filing dates.

4. The information disclosure statement, filed 5/6/05, is acknowledged. However, the Search Report citation has been lined through, as it has not been identified by author, title, publisher, date of publication, and relevant pages, as is required. See MPEP § 609.

5. The abstract of the disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP § 608.01(b).

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 24-36 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) An isolated antibody that selectively binds to a "polypeptide" (Claim 3, 24, 56-36, and dependant claims 25-34).

B) "A composition comprising the antibody...and a pharmaceutically acceptable carrier" (Claims 31-34).

It is noted that applicant has not cited any support for the new claims in the specification. A review of the specification fails to reveal support for the new limitations.

Regarding A), at page 27, the specification discloses "the invention also provides antibodies that selectively bind to one of the peptides of the present invention, a protein comprising such a peptide.." The specification does not appear to disclose antibodies to polypeptides, as now recited in the instant claims.

Regarding B), the specification as filed does not appear to provide a written description for the limitation of claims 31-34, where the antibody is part of a composition with a pharmaceutically acceptable carrier.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Tighilet et al. as evidenced by Karls et. al.

Tighilet teaches an antibody specific for residues 521-540 of mouse calcium/calmodulin dependent protein kinase II β subunit (CaMKII-β-see page 284). As evidenced by Fig. 1 of Karls, residues 521-540 of mouse CAMKII-β correspond exactly to residues 495-514 of SEQ ID NO: 2 of the instant application. Therefore said antibody would inherently bind to a polypeptide consisting or comprising SEQ ID NO: 2.

Thus the reference clearly anticipates the invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

> Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tighilet et. al in view of Gavilondo et. al.

The teachings of Tighilet are described above.

Tighilet does not teach a monoclonal antibody, an antibody coupled to a detectable substance, a composition comprising the antibody and a pharmaceutically acceptable carrier, or an isolated antibody fragment.

Gavilondo teaches the usefulness of monoclonal antibodies (see pg. 128) and antibody fragments (Table 1) for therapeutic, and diagnostic purposes (i.e. as compositions in a pharmaceutically acceptable carrier). In addition, Gavilondo teaches that antibodies can be fused with enzymes (i.e. detectably labeled-see pg. 135).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a monoclonal antibody, a composition thereof, an antibody fragment, or detectably labeled antibody as taught by Gavilondo to CAMKII-β protein as taught by Tighilet. The ordinary artisan at the time the invention was made would have been motivated to do so, since monoclonal antibodies, compositions thereof, labeled antibodies, and antibody fragments are extremely useful as diagnostic and therapeutic agents (see Gavilondo pgs. 128, 135-136, and Table 1). Moreover, one of ordinary skill in the art would have expected to succeed in generating said antibodies.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600
September 15, 2005

10/20/05
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

Notice to Comply	Application No. 10/760,470	Applicant(s) Shao et al.	
	Examiner Amy E. Juedes, Ph.D.	Art Unit 1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Numeric identifiers <150> and <151> are missing.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
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